UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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TYRIEKE CHANDLER,

Plaintiff,

- against -

MEMORANDUM & ORDER
15-CV-3106 (PKC) (SJB)

JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON, and JANSSEN RESEARCH & DEVELOPMENT, LLC,

Defendants.

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PAMELA K. CHEN, United States District Judge:

Plaintiff Tyrieke Chandler ("Plaintiff" or "Chandler") brings this matter alleging that Defendants Janssen Pharmaceuticals, Inc., Johnson & Johnson, and Janssen Research & Development, LLC (collectively "Defendants"), the manufacturers of antipsychotic prescription drug Risperdal®, failed to warn Plaintiff of the injurious side effects of the drug, including gynecomastia, a medical condition that causes the enlargement of breast tissue. The parties allege jurisdiction under 28 U.S.C. §§ 1332, 1441, and 1446 because the parties are of diverse citizenship and the amount in controversy exceeds $75,000. Before the Court is Defendants' motion for summary judgment. For the reasons set forth herein, the Court grants Defendants' motion for summary judgment in its entirety and all claims against Defendants are dismissed.

BACKGROUND

I. Relevant Facts

A. Risperdal®

Risperdal®[1] is a prescription antipsychotic medication that was first approved by the United States Food and Drug Administration ("FDA") in 1993 for use in adults. (Defendants' Rule 56.1 Statement ("Defs'. 56.1"), Dkt 46-2, at ¶ 1.)[2] Risperdal is generically known as risperidone. (*Id.* at ¶ 2.) Since 1993, Risperdal's FDA-approved labeling has contained the following language regarding the risk of gynecomastia and galactorrhea, a medical condition involving the excessive or inappropriate production of breast milk, in the "PRECAUTIONS" section:

> Hyperprolactinemia: As with other drugs that antagonize dopamine D2 receptors, risperidone elevates prolactin levels and the elevation persists during chronic administration. Tissue culture experiments indicate that approximately one-third of human breast cancers are prolactin dependent in vitro, a factor of potential importance if the prescription of these drugs is contemplated in a patient with previously detected breast cancer. Although disturbances such as galactorrhea, amenorrhea, gynecomastia, and impotence have been reported with prolactin-elevating compounds, the clinical significance of elevated serum prolactin levels is unknown for most patients. As is common with compounds which increase prolactin release, an increase in pituitary gland, mammary gland, and pancreatic islet cell hyperplasia and/or neoplasia was observed in the risperidone carcinogenicity studies conducted in mice and rats (See CARCINOGENESIS). However, neither clinical studies nor epidemiologic studies conducted to date have shown an association between chronic administration of this class of drugs and tumorigenesis in humans; the available evidence is considered too limited to be conclusive at this time.

(*Id.* at ¶ 3 (emphasis in original).) The 1993 Label also stated that the "safety and effectiveness [of Risperdal] in children have not been established." (*Id.* at ¶ 4.)

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[1] The Court hereafter does not include the trademark sign with each reference to Risperdal.

[2] Unless otherwise noted, a standalone citation to Defendants' 56.1 Statement (Dkt. 46-2) denotes that this Court has deemed the underlying factual allegation undisputed. Any citations to Defendants' 56.1 Statement incorporates by reference the documents cited therein. Where relevant, however, the Court may cite directly to the underlying document.

Risperdal was first approved for pediatric use—for irritability associated with autistic disorder—on October 6, 2006. (*Id.* at ¶ 5.) A subsection entitled "Pediatric Use" was added to the "PRECAUTIONS" section of Risperdal's label at that time. It states, in relevant part:

> The safety and effectiveness of RISPERDAL® in pediatric patients with schizophrenia or bipolar mania have not been established.
>
> The efficacy and safety of RISPERDAL® in the treatment of irritability associated with autistic disorder were established in two 8-week, placebo-controlled trials in 156 children and adolescent patients, aged 5 to 16 years (see CLINICAL PHARMACOLOGY - Clinical Trials, INDICATIONS AND USAGE, and ADVERSE REACTIONS). Additional safety information was also assessed in a long-term study in patients with autistic disorder, or in short- and long-term studies in more than 1200 pediatric patients with other psychiatric disorders who were of similar age and weight, and who received similar dosages of RISPERDAL® as patients who were treated for irritability associated with autistic disorder.
>
> . . .
>
> Hyperprolactinemia, Growth, and Sexual Maturation
>
> Risperidone has been shown to elevate prolactin levels in children and adolescents as well as in adults (see PRECAUTIONS - Hyperprolactinemia). In double-blind, placebo-controlled studies of up to 8 weeks duration in children and adolescents (aged 5 to 17 years) 49% of patients who received risperidone had elevated prolactin levels compared to 2% of patients who received placebo.
>
> In clinical trials in 1885 children and adolescents with autistic disorder or other psychiatric disorders treated with risperidone, galactorrhea was reported in 0.8% of risperidone-treated patients and gynecomastia was reported in 2.3% of risperidone-treated patients.
>
> The long-term effects of risperidone on growth and sexual maturation have not been fully evaluated.

(*Id.* (emphasis in original).)

In 2007, the label was changed, and the "WARNINGS" and "PRECAUTIONS" sections were merged. The label included the following language:

> WARNINGS AND PRECAUTIONS
>
> Hyperprolactinemia: As with other drugs that antagonize dopamine D2 receptors, RISPERDAL® elevates prolactin levels and the elevation persists during chronic

> administration. RISPERDAL® is associated with higher levels of prolactin elevation than other antipsychotic agents.
>
> * * * * *
>
> Galactorrhea, amenorrhea, gynecomastia, and impotence have been reported in patients receiving prolactin-elevating compounds.

(Risperdal Label 2007, Dkt. 52-18, at 1, 12.) The 2007 label contained the same information as the 2006 label about the clinical trial of 1885 children and adolescents, and the gynecomastia incidence rate of 2.3%. (*Id.* at 33.)

B. Plaintiff's Psychiatric History

Plaintiff was born in 1996. (Defs'. 56.1 at ¶ 6.) Plaintiff has a long history of psychological issues that began when he was six years old. (*Id.* at ¶ 8.) In June 2002, the Administration for Children's Services ("ACS") removed Plaintiff from his mother's home when his infant brother tested positive for marijuana at birth. (*Id.* at ¶ 9.) Plaintiff was housed in seven different foster homes over the next month and showed aggressive behavior toward adults and other children during this period. (*Id.* at ¶ 10.) In August 2002, Plaintiff was brought to the emergency room at Lincoln Medical and Mental Health Center ("Lincoln") because he was showing "uncontrollable behavior" toward his foster mother. (*Id.* at ¶ 11.) Plaintiff was released to the care of a new foster mother, but returned to Lincoln two days later for behavioral issues. (*Id.* at ¶¶ 15-16.) A subsequent psychiatric consultation diagnosed Plaintiff with Attention Deficit Hyperactive Disorder ("ADHD") and Depressive Disorder, and indicated that he "poses a danger to self and others." (*Id.* at ¶ 19.) Plaintiff was taking Adderall XR and Zoloft at the time. (*Id.* at ¶20.)

In February 2003, Plaintiff was hospitalized at St. Vincent's Hospital for a week after becoming "physically aggressive at school." (*Id.* at ¶ 22.) Plaintiff was diagnosed with ADHD and Oppositional Defiant Disorder. (*Id.* at ¶ 23.) Plaintiff's doctor discontinued Zoloft, decreased

Plaintiff's Adderall dosage, and prescribed Risperdal. (*Id.* at ¶ 24.) A few months later, in August 2003, Plaintiff was brought to New York Foundling Hospital, where he was placed on Adderall 20 mg and Risperdal 0.75 mg, which was soon thereafter increased to 1.5 mg. (*Id.* at ¶¶ 26-27.) In September 2003, Plaintiff's social worker noted that Plaintiff had "made a significant improvement in symptoms of hyperactivity, impulsivity and attention span" and noted his "positive response to the combination of psychotropic medication and routine, structure and consistent limit setting." (*Id.* at ¶ 28.) One of Plaintiff's doctors, Fatima Taylor, recommended that Plaintiff be placed in a residential treatment center and continue on psychotropic medications. (*Id.* at ¶ 30.)

In October 2003, Plaintiff was placed in The Children's Village in Dobbs Ferry. (*Id.* at ¶ 31.) The psychiatrists at Children's village continued prescribing Plaintiff Adderall and Risperdal. (*Id.* at ¶ 32.) In April 2004, Children's Village psychiatrist Dr. Mary Lincoln noted that Plaintiff was prescribed Adderall 30 mg and Risperdal 2 mg to treat his symptoms of ADHD and aggression. (*Id.* at ¶ 33.) Dr. Lincoln noted that Plaintiff's issues seemed to worsen in the absence of regular contact with his mother, and diagnosed Plaintiff with ADHD and Oppositional Defiant Disorder. (*Id.* at ¶¶ 33-34.) Between August and October 2004, Plaintiff's aggression appeared to decline, so Plaintiff's doctor decreased Plaintiff's Risperdal dose to 0.5 mg. (*Id.* at ¶¶ 35-36.) But, in November 2004, Plaintiff's behavior deteriorated; his therapist noted that his behavior was "explosive and unsafe." (*Id.* at ¶ 38.) In December 2004, Plaintiff was admitted to the Crisis Residence section of Children's Village for behavioral issues at a Thanksgiving dinner after he learned he could not visit his birth mother. (*Id.* at ¶ 39.) Progress notes from February 2005 state that Plaintiff's noncompliance with his medication was "associated w[ith] dramatic behavioral deterioration" and that Plaintiff's grandmother stated that Plaintiff "kicked her and threw [a]

tantrum" on his last home visit. (*Id.* at ¶ 40.) Less than a year later, in January 2006, Plaintiff's grandmother stated that on a recent home visit, Plaintiff threw chairs, took the hinges off a door, grabbed her by the collar, and threatened to break her glasses. (*Id.* at ¶ 41.) Children's Village psychiatrists increased Plaintiff's Risperdal dosage to 2 mg per day to compensate for his behavior issues. (*Id.* at ¶ 42.)

Dr. Robert Miller, a child psychiatrist at Children's Village, treated Plaintiff between July 2005 and September 2008. (*Id.* at ¶ 44.) In November 2006, Dr. Miller observed that Plaintiff's general level of aggression might be increasing. (*Id.* at ¶ 45.) Dr. Miller continued Plaintiff's maintenance medications of Risperdal 2 mg and Adderall 30 mg. (*Id.* at ¶ 46.) In February 2007, Plaintiff was admitted again to the Crisis Residence at Children's Village after learning that he might not be able to leave Children's Village in the custody of his grandmother. (*Id.* at ¶ 48.) Dr. Miller diagnosed Plaintiff with an adjustment disorder and when his symptoms did not improve, he was hospitalized on March 8, 2007 "for safety concerns." (*Id.* at ¶¶ 49-50.) While hospitalized, Plaintiff's Risperdal was increased to 4 mg daily and he was also prescribed Prozac 20 mg. (*Id.* at ¶ 51.) Plaintiff's condition improved briefly in April 2007. (*Id.* at ¶ 52.) But, in June 2007, Plaintiff was again placed in the Crisis Residence for "aggressive behavior." (*Id.* at ¶ 53.) Dr. Miller continued Risperdal at 4 mg daily, along with Adderall 30 mg and Prozac 20 mg. (*Id.* at ¶ 55.)

In July 2007, Plaintiff was hospitalized at Stony Lodge Hospital for a month. (*Id.* at ¶ 56.). Dr. Miller noted Plaintiff's new medication of Zoloft 100 mg, and continued prescribing Risperdal 4 mg and Adderall 30 mg. (*Id.*) In March 2008, Dr. Miller reduced Plaintiff's Risperdal dose from 4 mg to 3 mg. (*Id.* at ¶ 65.) In July 2008, Dr. Miller noted that Plaintiff was doing well, but did not want to lower his medication in view of his upcoming discharge into the care of his

grandmother. (*Id.* at ¶ 66.) That same month, Plaintiff's prolactin levels were measured and found to be 23.3 ng/mL, within normal range for a child. (*Id.* at ¶ 119.)

In October 2008, Plaintiff was discharged from Children's Village into the care of his grandmother. (*Id.* at ¶ 67.) His medications at that time were Adderall 30 mg; Risperdal 3 mg; and Zoloft 100 mg. (*Id.* at ¶ 68.)

On June 12, 2009, Plaintiff saw psychiatrist Dr. Robert Neal. (*Id.* at ¶ 102.) Plaintiff complained of enlarged breasts. Dr. Neal asked Plaintiff to lift his shirt and documented the breast enlargement. (*Id.* at ¶ 103.) Dr. Neal noted that Plaintiff "continues to have disabling psychiatric signs and symptoms," and recommended that Plaintiff discontinue Risperdal, which he observed was "probably responsible for the breast enlargement." (*Id.* at ¶ 105.) Dr. Neal also recommended Plaintiff discontinue Zoloft, but continue taking Adderall. Dr. Neal noted that he had been aware of the correlation between Risperidone and breast enlargement for several years prior to June 2009. (*Id.* at ¶ 100.) In August of 2009, after Plaintiff had stopped taking Risperdal, his prolactin levels were measured for a second time and were found to be 6.75 ng/mL, within normal range. (*Id.* at ¶ 120.)

Plaintiff continued to see other doctors throughout 2009 and 2010. In December 2009, Dr. Rhonda Cambridge Phillip noted that Plaintiff was taking a new antipsychotic medication, Haldol, which could be contributing to his gynecomastia. (*Id.* at ¶ 109.) In April 2010, Dr. Amish Nishawala stated that Plaintiff had stopped taking Haldol because of its "potential effect on his gynecomastia," but that his behavior had worsened. (*Id.* at ¶ 111.) In December 2011, Plaintiff was hospitalized at Kings County Hospital after his grandmother reported that he had been violent at home. (*Id.* at ¶ 112.) In January 2012, Dr. Neal reduced the prescribed amount of Seroquel, yet

another antipsychotic, and added lithium because Plaintiff was exhibiting noticeable weight gain. (*Id.* at ¶ 113.)

In February 2012, Plaintiff complained to Dr. Neal again about his enlarged breasts. (*Id.* at ¶ 114.) Dr. Neal diagnosed Plaintiff with bipolar disorder and mania, and increased Plaintiff's lithium dose while maintaining his Seroquel and Depakote. (*Id.* at ¶ 115.) In March 2012, Dr. Neal saw Plaintiff for the last time and noted that Plaintiff complained that his breasts continued to enlarge. (*Id.* at ¶ 116.) On May 7, 2012, Plaintiff's prolactin levels were tested for a third time and found to be 8.0 ng/mL, within normal range for a boy his age. (*Id.* at ¶ 121.) In September 2012, Plaintiff ceased taking any medication due to pancreatitis, which his physicians associated with lithium and Depakote. (*Id.* at ¶ 118.)

In April 2014, Plaintiff underwent bilateral mastectomies to remove his enlarged breast tissue at Mount Sinai Hospital. (Plaintiff's Rule 56.1 Statement ("Pl's. 56.1"), Dkt. 53, at ¶ 124.)

II. Procedural History

Plaintiff filed his complaint in this action on March 30, 2015 in Kings County Supreme Court. (Dkt. 1.) On May 28, 2015, Defendants removed this case to federal court based on diversity jurisdiction under 28 U.S.C. §§ 1332, 1441, and 1446. (Dkt. 1.) On June 24, 2015, Plaintiff filed an amended complaint. (Dkt. 11.) Defendants answered the amended complaint on July 1, 2015. (Dkt. 12.) The parties completed discovery on July 7, 2017. Defendants' motion for summary judgment was fully briefed on December 18, 2017. (Dkts. 46, 49.) At Defendants' request (Dkt. 51), the Court held oral argument on the motion for summary judgment on June 11, 2018.

STANDARD OF REVIEW

"Summary judgment is appropriate where there are no genuine disputes concerning any material facts, and where the moving party is entitled to judgment as a matter of law." *Summa v.*

Hofstra Univ., 708 F.3d 115, 123 (2d Cir. 2013) (quoting *Weinstein v. Albright*, 261 F.3d 127, 132 (2d Cir. 2001)); *see also* Fed. R. Civ. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986). "Material" facts are facts that "might affect the outcome of the suit under the governing law." *Anderson*, 477 U.S. at 248. A "genuine" dispute exists "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* "The moving party bears the burden of establishing the absence of any genuine issue of material fact." *Zalaski v. City of Bridgeport Police Dep't*, 613 F.3d 336, 340 (2d Cir. 2010) (citing *Celotex Corp.*, 477 U.S. at 322). Once a defendant has met his initial burden, the plaintiff must "designate specific facts showing that there is a genuine issue for trial." *Celotex Corp.*, 477 U.S. at 324 (internal quotation marks omitted). In determining whether there are genuine disputes of material fact, the court must "resolve all ambiguities and draw all permissible factual inferences in favor of the party against whom summary judgment is sought." *Terry v. Ashcroft*, 336 F.3d 128, 137 (2d Cir. 2003) (citation and internal quotation marks omitted). "Summary judgment is appropriate only '[w]here the record taken as a whole could not lead a rational trier of fact to find for the non-moving party.'" *Donnelly v. Greenburgh Cent. Sch. Dist. No. 7*, 691 F.3d 134, 141 (2d Cir. 2012) (alterations in original) (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986)).

DISCUSSION

I. Legal Standards Regarding Failure to Warn in New York[3]

"Under New York law, a pharmaceutical manufacturer has a duty 'to warn of all potential dangers in its prescription drugs that it knew, or, in the exercise of reasonable care, should have

[3] Given that this is a tort action brought in federal court pursuant to diversity jurisdiction, New York law applies with regard to Plaintiff's failure to warn claim. *See e.g.*, *DiBartolo v. Abbott*

known to exist.'" *DiBartolo v. Abbott Labs.*, 914 F. Supp. 2d 601, 611 (S.D.N.Y. 2012) (quoting *Martin v. Hacker*, 83 N.Y.2d 1, 8 (1993)). The manufacturer's duty to warn "is fulfilled by giving adequate warning through the prescribing physician, not directly to the patient." *Abrams v. Bute*, 27 N.Y.S.3d 58, 65 (2016) (citations omitted); *Dibartolo*, 914 F. Supp. 2d at 611 ("The New York Court of Appeals has adopted the Informed Intermediary Doctrine . . . also known as the 'Learned Intermediary Doctrine,' which provides that a drug manufacturer's duty is to warn the treating physician, not the patient."). Pursuant to the "Learned Intermediary Doctrine," "a manufacturer's duty is to warn only of those dangers it knows of or are reasonably foreseeable." *Davids v. Novartis Pharm. Corp.*, 857 F. Supp. 2d 267, 286 (E.D.N.Y. 2012).

A prescription medicine warning is adequate as a matter of law "if it provides specific detailed information on the risks of the drug." *Martin*, 83 N.Y.2d at 10. Specifically, "prescription medicine warnings are adequate when . . . information regarding 'the precise malady incurred' was communicated in the prescribing information." *Alston v. Caraco Pharm., Inc.*, 670 F. Supp. 2d 279, 284 (S.D.N.Y. 2009) (citation omitted). In making this determination, the Court should consider factors including "whether the warning is accurate, clear, consistent on its face, and whether it portrays with sufficient intensity the risk involved in taking the drug." *Martin*, 83 N.Y.2d at 10. A warning is accurate if it is "correct, fully descriptive and complete, and . . . convey[s] updated information as to all of the drug's known side effects." *Id.* at 11 (citation omitted). It is clear if it is "direct, unequivocal and sufficiently forceful to convey the risk." *Id.*

Courts must evaluate the entire warning, as any vagueness that appears from reading individual sentences in isolation "may be overcome if, when read as a whole, the warning conveys

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Labs., 914 F. Supp. 2d 601, 611 (S.D.N.Y. 2012) (applying New York law to a failure to warn claim).

a meaning as to the consequences that is unmistakable." *Id.* at 12. An otherwise clear warning "may be obscured by inconsistencies or contradictory statements made in different sections of the package insert regarding the same side effect or from language in a later section that dilutes the intensity of a caveat made in an earlier section." *Id.* at 11. Ordinarily, the adequacy of a warning is a question of fact left to the jury, unless the warning so clearly and accurately conveys the risk of the complained-about injury that reasonable persons could not disagree as to the adequacy of that label. *See Bukowski v. CooperVision, Inc.*, 592 N.Y.S.2d 807, 808 (3d Dep't 1993).

To state a prima facie claim for failure to warn, "[a] plaintiff must demonstrate [1] that the warning was inadequate and [2] that the failure to adequately warn of the dangers of the drug was a proximate cause of his or her injuries." *DiBartolo*, 914 F. Supp. 2d at 611–12 (quoting *Glucksman v. Halsey Drug Co.*, 553 N.Y.S.2d 724, 726 (1990)). The Court will address each of these requirements in turn.

II. Plaintiff Cannot Establish that Risperdal's Warning Was Inadequate

Plaintiff's failure to warn claim alleges that Risperdal's labels, both before and after October 2006, the time at which Risperdal was approved for pediatric use, were inadequate because they insufficiently described the incidence rate of gynecomastia. Plaintiff, who began taking Risperdal in 2003 and began developing breasts in 2005, asserts that prior to October 2006, Defendants never issued a warning that Risperdal was for adult use only and attempted to "'downplay' the real risk associated with the drug." (Pl. Opp'n Mot., Dkt. 52, at 35.) Plaintiff argues it was not enough for Defendants to "generally" warn of the risks of gynecomastia and elevated prolactin levels on the label, because the drug was "illegally marketed" to children prior to 2006. (*Id.*) Further, Defendants allege, the drug's label did not contain any mention of gynecomastia, hyperprolactinemia, and/or precocious puberty under the "WARNINGS" or

"ADVERSE REACTIONS" sections of the label. (*Id.* at 8, 35.) Plaintiff claims that a drug company cannot provide an adequate warning by mentioning a significant risk "in passing." (*Id*.)

Regarding Risperdal's post-October 2006 label, Plaintiff claims that Defendants omitted specific and important risk information and failed to timely update the information on the label when it had knowledge of the risks. (*Id.* at 34.) In particular, Plaintiff cites two studies showing that gynecomastia incidence rates were between two and five times higher than the rate of 2.3% listed on Risperdal's post-October 2006 label. One study allegedly showed that gynecomastia incidence rates were 4.8% in children and adolescents, while the other study allegedly concluded that the rate was closer to 12.5%. (*Id.* at 36.) Plaintiff argues that these rates were significantly higher than what Dr. Miller, Plaintiff's prescribing physician, thought they were at time, and that had Dr. Miller been advised by Defendants of the higher rates, he would have changed his prescribing decisions. (*Id.*)

In their summary judgment motion, Defendants argue that Plaintiff has not produced admissible evidence demonstrating that the warning on Risperdal's label was inadequate, which is fatal to his failure to warn claim. (Def. Mot. S.J., Dkt. 46-1, at 20.) Defendants note that since Risperdal's approval by the FDA in 1993, the risk of gynecomastia, in fact, has been communicated to physicians in the "PRECAUTIONS" section of the label. (*Id.* at 8.) Defendants argue that the only "evidence" Plaintiff offers to support his claim that the label did not adequately warn of the risk of gynecomastia are the two clinical studies that Plaintiff contends show a higher incidence of gynecomastia—a contention that is inadmissible without expert testimony. (Defs'. Reply, Dkt 49, at 9-10.) Defendants dispute Plaintiff's characterization and "cherry pick[ing]" of these studies, noting that the two were part of a group of eighteen clinical studies on the side effects

of Risperdal that were considered by Defendants and the FDA when determining the appropriate incidence rate of gynecomastia to include on Risperdal's label. (*Id.*)

As an initial consideration, the Learned Intermediary Doctrine as applied in this case precludes Plaintiff from recovering for any injuries sustained from the use of Risperdal unless he can show that the warnings were inadequate as to his prescribing physicians. *Davids*, 857 F. Supp. 2d at 286. Plaintiff has offered Risperdal's FDA-approved labels as evidence of warnings provided to physicians contemporaneous with or predating Plaintiff's use of Risperdal. These labels are from 1999, 2002, 2006, and 2007. Given that Plaintiff began taking Risperdal in 2003, the relevant warning labels are from 2002, 2006, and 2007. Under these circumstances, the Court takes judicial notice of the FDA-approved labels introduced by Plaintiff.[4] *See Becker v. Cephalon, Inc.*, No. 14-CV-3864 (NSR), 2015 WL 5472311, at *3 (S.D.N.Y. Sept. 15, 2015) (taking judicial notice of FDA-approved labels in assessing failure to warn claim "because the labels 'can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.'") (quoting Fed. R. Evid. 201(b)(2)).

The Court finds that Plaintiff cannot prove that Risperdal's 2002, 2006, and 2007 labels were inadequate. Gynecomastia is identified in the 2002 Risperdal label. (Defs'. Rule 56.1, at ¶ 3.) The 2002 label, which was in effect at the time Plaintiff began taking Risperdal in 2003, included a detailed list of possible side effects – including gynecomastia, galactorrhea, and hyperprolactinemia, among others – under the "PRECAUTIONS" section of the label. (*Id.*) The FDA-approved label for Risperdal warns about the risk of gynecomastia and further explains that

[4] The Court notes that federal regulatory clearance of a medication from the FDA does not shield the manufacturer from liability under state law. *Wyeth v. Levine*, 555 U.S. 555 (2009) (holding that federal law did not pre-empt Plaintiff's claim that anti-nausea drug Phenergan's label did not contain an adequate warning).

such conditions have been reported with prolactin-elevating compounds. *See Alston*, 670 F. Supp. 2d at 284 ("[P]rescription medicine warnings are adequate when, as here, information regarding 'the precise malady incurred' was communicated in the prescribing information.") (quoting *Wolfgruber v. Upjohn Co.*, 423 N.Y.S.2d 95, 96–97 (4th Dep't. 1979)). Indeed, Plaintiff's prescribers, along with the larger medical community at Children's Village, were always aware of the possible risk of gynecomastia. (Pl's. 56.1, at ¶¶ 82, 86, 100; Deposition of Dr. Robert Miller ("Robert Miller Dep."), Dkt. 46-9, at 23:17-24:9 (Dr. Miller was aware that Risperdal could cause gynecomastia before the onset of Plaintiff's breast enlargement).) Thus, because the 2002 label warned that the product could cause gynecomastia, it satisfied Defendants' duty to provide adequate warnings to treating physicians regarding a possible risk of the product. *Fane v. Zimmer*, 927 F.2d 124, 129 (2d Cir. 1991) (finding drug manufacturer "absolved from liability as a matter of law" where it provided plaintiff's physician with "specific detailed information on the risks of the [product]"); *Stahl v. Novartis Pharmaceuticals Corp.*, 283 F.3d 254, 266 (5th Cir. 2002) ("[A[drug warning is adequate as a matter of law if it clearly and unambiguously notifies the prescribing physician of the particular adverse reaction that forms the basis of the plaintiff's complaint."); *Sita v. Danek Medical, Inc.*, 43 F. Supp. 2d 245, 260 (E.D.N.Y.1999) (granting summary judgment because defendant warned physician "against the precise usage and injuries in question").

To the extent Plaintiff argues that the 2002 label was inadequate because it did not include information about the 2.3% incidence rate of gynecomastia, even though Defendants were allegedly marketing Risperdal "illegally", *i.e.*, pre-indication for children, to children,[5] the Court

[5] The Court notes that Plaintiff does not argue in his opposition brief that the 2002 Risperdal label failed to convey "with sufficient intensity the risk involved in taking the drug", *McDowell v. Eli Lilly and Co.*, 58 F. Supp. 3d 391, 403 (S.D.N.Y. 2014), because it merely warned of the possibility of gynecomastia, and not the 2.3% incidence rate. At oral argument, however, in response to the Court's questioning on this issue, Plaintiff's counsel suggested that because a 2.3%

rejects those arguments. Under New York law, drug manufacturers must "keep abreast of knowledge of [their] products as gained through research, adverse reaction reports, scientific literature and other available methods," as well as "take such steps as are reasonably necessary to bring that knowledge to the attention of the medical profession." *Baker v. St. Agnes Hosp.*, 421 N.Y.S.2d 81, 85 (1979). Even though clinical trials testing the potential side effects of Risperdal on children date back as far as 1997 (*see* Dkt. 52-12), Plaintiff offers no evidence that Defendants consciously chose to omit information from the 2002 label regarding the incidence rate of gynecomastia. In seeking FDA approval for children's use of Risperdal before October 2006, Defendants were clearly "keep[ing] abreast of knowledge" of the drug through available methods and taking steps to "bring that knowledge to the attention of the medical profession." *Baker*, 421 N.Y.S. at 85. Indeed, the eighteen tests examining the potential side effects of Risperdal in children were conducted pursuant to the FDA's approval process and demonstrate that Defendants sought to determine the accurate incidence rate of gynecomastia in children for the 2006 label. As a result, the Court finds that Plaintiff has not demonstrated that there is a genuine issue of material fact related to whether Defendants "knew, or, in the exercise of reasonable care, should have known" of higher incidence rates of gynecomastia caused by Risperdal before it introduced its label in 2006 and made the drug available for pediatric use. *Martin*, 83 N.Y.2d 1 at 8.

With respect to Risperdal's 2006 and 2007 labels, which warned of a 2.3% incidence rate of gynecomastia, Plaintiff has not produced admissible evidence that these warnings were inadequate. As a general matter, expert testimony is required when the factual content of the

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incidence rate translates into one out of every fifty children getting gynecomastia, it should have been included on all of Risperdal's labels. Plaintiff, however, has not offered any caselaw to support the conclusion that a 2.3% incidence rate is sufficient to trigger a duty to specifically warn about a rate of incidence, especially where the rate of incidence relates only to a sub-population, here, children, for whom the drug was not approved during the period at issue.

underlying issues is not found within common knowledge and experience of laypersons. *Fane*, 927 F.2d at 131-32 (affirming the trial court's directed verdict for the defendant in a product liability case because, absent expert medical testimony on the issue of causation, the plaintiffs could not prove the elements of strict liability or negligence). Even though a "jury does not need expert testimony to find a label inadequate," *Billiar v. Minnesota Min. and Mfg. Co.*, 623 F.2d 240, 247 (2d Cir. 1980), courts routinely have held that conclusory opinions from counsel or experts are not enough to create a genuine issue of material fact in a failure to warn claim, *see e.g.*, *Browning v. Wyeth, Inc.*, 831 N.Y.S.2d 804, 804 (2007) (affirming summary judgment in drug manufacturer's favor and holding that the warning "portrayed with 'sufficient intensity' the risks involved in taking the drugs" and that "the conclusory opinion of plaintiff's expert was insufficient to raise an issue of fact.").

Plaintiff argues that Defendants should have changed the Risperdal label—which the Court construes for purposes of Plaintiff's claim as referring to the 2002, 2006, and 2007 labels—as developing research on Risperdal indicated that the drug caused gynecomastia at a higher rate of incidence than 2.3%. Plaintiff offers two studies that allegedly show incidence rates higher than 2.3% for gynecomastia.[6] The two studies were part of a group of eighteen studies that were conducted around the same time, all assessing the potential side effects of Risperdal, such as gynecomastia. However, Plaintiff introduces no expert testimony on the validity of these studies, either standing alone or compared to the other sixteen studies, or the regulatory requirements of labeling.[7] Without an expert, Plaintiff cannot opine on the statistical or methodological differences

[6] The first study ran clinical trials from 1997 to 2001, and the second study did so from 2000 to 2002. (*See* Dkts. 52-12 to 52-15.)

[7] Plaintiff's expert, Dr. Bradley Miller, testified at his deposition that he was unable to offer an opinion as to the adequacy of the warnings to either physicians or consumers because he had

between the studies or why the two studies he cited were correctly decided in comparison to the other sixteen. *See Montagnon v. Pfizer, Inc.*, 584 F. Supp. 2d 459, 463 (D. Conn. 2008) (granting motion for summary judgment where Plaintiff did not introduce expert testimony to interpret two studies suggesting that drug could lead to greater bone density loss than indicated by the warning label). Indeed, Plaintiff does not attempt to rebut the other sixteen studies that drew different conclusions from Plaintiff's warnings. *Krasnopolsky v. Warner–Lambert Co.*, 799 F.Supp. 1342, 1346–47 (E.D.N.Y. 1992) (granting summary judgment and finding that "speculative and conclusory claims of possible inadequacies in the warning without any evidentiary backup does not create a genuine factual issue so as to preclude summary judgment"). To be clear, while the two studies could be evidence of higher incidence rates, the absence of an expert to interpret and validate them precludes their admission.

The Court finds that this issue should not be left to a jury. Neither the Court nor a lay jury is capable of assessing the credibility of the two studies, synthesizing the results of the studies (which do not plainly identify any of the proposed warnings), or comparing the results of these studies with other studies that came to contrary conclusions. The Court is also in no position to second-guess the FDA-approved label that lists the 2.3% incidence rate of gynecomastia. The FDA, staffed by medical experts, "frequently takes years to carefully consider the evidence gleaned from multiple studies and reports before approving the form of a final warning."

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not reviewed them. (Deposition of Dr. Bradley Miller, Dkt. 46-15, at 106:1-4) (Q: . . . [Y]ou do not intend to offer any opinions, relating to the labelling for Risperdal in this matter? A: No, sir.").) But even if Plaintiff's expert had opined on FDA regulations or the adequacy of the warning label from a regulatory perspective, this Court would have had to exclude this testimony. *See Watkins v. Cook Inc.*, No. 13–CV–20370 (JG), 2015 WL 1395773, at *10 (S.D.W.Va. Mar. 25, 2015) (allowing doctor to opine on label based on knowledge and experience with product, but not on FDA regulations); *In re Mirena IUD Products Liability Litigation*, 169 F. Supp. 3d 396, 423 (S.D.N.Y. 2016) (defendants' medical experts may not "opine on FDA regulations or whether the Mirena label complied with them, as these doctors are not qualified as experts on that subject").

Montagnon, 584 F. Supp. 2d at 463. Even if expert testimony were not required as a matter of law, the Court finds that no jury of laypersons, on the basis of only two studies, which have not been interpreted by expert testimony, could reasonably decide that Defendants should have rewritten their warnings at some point before 2007. *See Gold v. Dalkon Shield Claimants Trust*, No. B–82–383 (EBB), 1998 WL 351456 at *3 (D.Conn. Jun. 15, 1998) (granting summary judgment where no expert testimony was offered to prove that a birth control device malfunctioned and holding that "[m]edical evidence relating to causes of injury to the human body is not normally considered to dwell within the common knowledge of a layperson").

In sum, Plaintiff has failed to demonstrate a material issue of fact in dispute as to whether the 2002, 2006, and 2007 Risperdal labels adequately conveyed the risk of gynecomastia to prescribing medical professionals. Indeed, the undisputed evidence demonstrates that these labels warned of the "precise malady" that Plaintiff "incurred".[8] For this reason alone, Defendants are entitled to summary judgment with respect to Plaintiff's failure to warn claim.

III. Plaintiff Cannot Establish Causation

Even if the warning on the Risperdal label was somehow lacking, Plaintiff must also show that Defendants' failure to provide a sufficient warning to Plaintiff's prescribing physicians was the proximate cause of his injury. *Figueroa v. Bos. Sci. Corp.*, 254 F. Supp. 2d 361, 370 (S.D.N.Y. 2003). In asserting a failure to warn claim, a plaintiff must prove both general causation and specific causation. *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 252 n.1 (2d Cir. 2005). General causation "bears on whether the type of injury at issue can be caused or exacerbated by the defendant's product," while specific causation addresses "whether, in the particular instance,

[8] In reaching this conclusion, the Court is sympathetic to Plaintiff's personal circumstances. The Court, however, must follow the law as it applies to his failure to warn claim.

the injury actually was caused or exacerbated by the defendant's product." *Id.* Further, proof of general causation is a "necessary predicate for that of specific causation – if there is no evidence that a product is capable of causing the kind of harm claimed, then there is no basis to accept evidence that the product in fact did so in a specific case." *In re Rezulin Products Liability Litigation*, 441 F. Supp. 2d 567, 575 (S.D.N.Y. 2006).

A. General Causation is Established

When a case rests on complex medical issues, the plaintiff must introduce evidence, including expert medical testimony, establishing causation. *Fane*, 927 F.2d at 131. Plaintiff's expert, Dr. Bradley Miller[9], concluded that Risperdal can cause gynecomastia. (*See* Dkt. 52-24.) Moreover, it is undisputed that in 2006, Defendants added the following to its "PRECAUTIONS" section: "gynecomastia was reported in 2.3% of risperidone-treated patients." (Defs'. 56.1, at ¶ 5.) As a result, it is clear that Plaintiff has satisfied the requirements for proving general causation in this case, since "the type of injury at issue [*i.e.*, gynecomastia] can be caused or exacerbated by the defendant's product [*i.e.*, Risperdal]." *Ruggiero*, 424 F.3d at 252 n.1. Because Plaintiff has shown proof of general causation, he has met the "necessary predicate" to show specific causation, which the Court now considers.

B. Plaintiff Cannot Establish Specific Causation

Under New York's proximate cause standard, a defendant in a failure to warn case is entitled to summary judgment if the evidence establishes "that any given warning would have been futile – [1] either because any such warnings would not have been heeded or [2] because the injury would have occurred, regardless of the given warnings." *Bee v. Novartis Pharms. Corp.*, 18 F.

[9] Given that Plaintiff's psychiatrist is Dr. Robert Miller, the Court refers to Dr. Bradley Miller as "Plaintiff's expert".

Supp. 3d 268, 284 (E.D.N.Y. 2014). On the first prong, "a plaintiff must demonstrate that had a different, more accurate warning[] been given, his physician would not have prescribed the drug in the same manner." *Alston*, 670 F. Supp. 2d at 285; *see also Mulhall v. Hannafin*, 841 N.Y.S.2d 282, 287 (2007) ("[P]laintiffs had to show that had the warning been different, [the treating physician] would have departed from her normal practice and used another device."). On the second prong, if the treating physician is aware of the risks of a drug, independent of any warning by the manufacturer, "such knowledge constitutes an intervening event relieving the manufacturer of any liability to a patient under a failure to warn theory." *Banker v. Hoehn*, 718 N.Y.S.2d 438, 440–41 (3d Dep't 2000).

Here, there is no evidence that had Defendants given a "different, more accurate warning" for Risperdal, Plaintiff's physicians would not have prescribed the drug in the same manner. Drs. Miller and Neal testified that they had knowledge of the side-effects of Risperdal, including gynecomastia, both before and during the time that they prescribed the drug. Dr. Neal testified that he was aware of the "possible correlation" between Risperdal and gynecomastia for "[a]t least a couple of years" prior to June 2009. (Deposition of Dr. Robert Neal ("Neal Dep."), Dkt. 46-16, at 26:13-27:3.) Dr. Neal stated that he was not sure he would have changed his decision even if he knew the risk was higher. Rather, he would have done a "risk/benefit analysis and considered [gynecomastia] as a potential risk and weighed it against the potential benefits of keeping [Plaintiff] on the medicine." (*Id.* at 30:17-31:2.) Dr. Miller similarly stated that he knew of the effects of Risperdal "[p]robably since shortly after it came out" and that his "knowledge of the association between Risperdal and gynecomastia" had not changed over time. (Robert Miller Dep., at 23:18-24:9.) Dr. Miller, however, testified that he did not learn of the risk of gynecomastia from Risperdal's label and thought that the risk was less than 1% ten years after the label was

changed to reflect a possible 2.3% risk. (*Id.* at 111:19-112:23.) Dr. Miller did not read the warnings on any of Risperdal's labels, but rather was aware of the risks and benefits of Risperdal from his education, medical training, and clinical experience. (*Id.*)

Furthermore, despite knowing of the risk of gynecomastia associated with Risperdal, Dr. Miller did not inform Plaintiff of that risk. In his deposition, Dr. Miller testified:

> Q. And, doctor, let me ask you this . . . When you first prescribed medication for [Plaintiff], the Risperdal you did not advise him or his guardian that gynecomastia was a potential side effect?
>
> A. That is correct.
>
> Q: And regardless of whether you called it gynecomastia or something else, you never told [Plaintiff] or one of his guardians that breast tissue, abnormal breast growth is something they should be looking out for?
>
> A: That is correct.
>
> Q: You told us earlier that with the introduction of Risperdal as a drug to the market here in the United States you became aware of gynecomastia as a potential side-effect, is that fair to say?
>
> A: Correct.

(*Id.* at 116:23-117:17.)

Both Dr. Miller's failure to read Risperdal label and advise Plaintiff of this potential adverse effect, despite knowing of it, constitutes an intervening cause severing the causal connection between Defendants' alleged failure to warn and Plaintiff's injury. *Ohuche v. Merck & Co.*, 903 F. Supp. 2d 143, 151-52 (S.D.N.Y. 2012) (finding that manufacturer's alleged failure to adequately disclose risks of drug Zostavax was not the proximate cause of Plaintiff's injuries where physician testified "that she was aware of the adverse reactions associated with [the drug]"); *Glucksman v. Halsey Drug Co.*, 553 NY.S.2d 724, 726 (1st Dep't 1990) (applying the informed intermediary doctrine where the treating physician "testified that he was independently aware of

the dangers involved" despite his "decision not to inform the plaintiff of the risk" of a side effect the patient ultimately experienced); *see also Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 468 (5th Cir. 1999) (no proximate cause where physician was independently aware of possible risks of using medical device through experience and review of literature); *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir. 1992) ("[T]he manufacturer cannot be said to have caused the injury if the doctor already knew of the medical risk.").

Nonetheless, Plaintiff argues that even though Dr. Miller did not read the warning labels, he *would have* changed the way he prescribed the drug if he knew that the incidence rates of gynecomastia were much higher than he previously thought.[10] There are at least two problems with this argument. First, whether Dr. Miller hypothetically would have changed his prescribing behavior is irrelevant to the question of whether Defendants' label *actually* caused Plaintiff's injury, given that Dr. Miller never read the label, independently knew of the risk of gynecomastia, and never informed Plaintiff or his guardian about any risk of gynecomastia. Second, to the extent Plaintiff is relying on the higher-than-2.3% incidence rates to make this argument, he runs into the same problem discussed earlier: he has no expert who can interpret or validate the two studies allegedly showing these higher incidence rates, thus making it improper to argue that Dr. Miller's prescribing practice would or should have been different had the label included these higher incidence rates. Put differently, because there is no basis for concluding that these higher rates are valid and that the Risperdal label therefore should have included them, it is again irrelevant that

[10] As the Court explains *supra*, to the extent Plaintiff argues that causation is supported by the marketing materials for Risperdal allegedly distributed by Defendants, even assuming that this material could be considered in connection with Plaintiff's false labeling claim, the record similarly indicates that Dr. Miller never saw or read those materials. (Robert Miller Dep., at 103:16-104:8 (stating that he did not have contact with Janssen sales representatives or marketing material about Risperdal).)

Dr. Miller would have changed his mind about prescribing Risperdal had he known of these higher rates.

Lastly, the fact that Plaintiff's guardian, according to her affirmation, would not have consented to the Risperdal prescription had Dr. Miller advised her of the risk of gynecomastia is irrelevant to Plaintiff's claims against Defendants. *See Salva v. Blum*, 716 N.Y.S.2d 527, 528 (4th Dep't 2000) ("Lack of informed consent is not a theory of liability upon which an injured person may sue the manufacturer of a defective product."). A failure to obtain informed consent might be a viable theory of liability against the physician or the hospital where the operation was performed. However, neither Dr. Miller nor Children's Village is a party to this lawsuit.

In sum, Plaintiff cannot establish specific causation and, on this basis alone, Defendants are entitled to summary judgment.[11]

[11] With respect to specific causation, Defendants also argue that Plaintiff's expert fails to explain how Risperdal could have cause Plaintiff's gynecomastia in the absence of prolactin elevation, a fact not in dispute, and that the expert's alternative theory is pure speculation. (Defs'. Mot. S.J., at 20-21.) The Court has found that Plaintiff is unable to demonstrate specific causation because of his physicians' failure to read Defendants' label, their independent knowledge or belief about the risk of gynecomastia, and their failure to inform Plaintiff or his guardian of the risk, and therefore does not address Defendants' arguments about the deficiencies in the opinion testimony of Plaintiff's expert. The Court, however, notes that Plaintiff's argument that his expert is able to establish a link between Plaintiff's consumption of Risperdal and the change in his prolactin levels misses the point. The issue of whether Plaintiff's consumption of Risperdal caused Plaintiff's gynecomastia is not the same as whether Defendants' alleged failure to sufficiently warn about the risk of gynecomastia caused Plaintiff's gynecomastia, which is the only relevant issue here.

CONCLUSION

For the reasons stated herein, Defendants' motion for summary judgment is granted, and all claims against Defendants are dismissed.

SO ORDERED.

/s/ Pamela K. Chen
Pamela K. Chen
United States District Judge

Dated: June 29, 2018
Brooklyn, New York